

**REMARKS**

This Amendment is filed in response to the non-final Office Action dated April 15, 2008, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

In the present Amendment, claims 1 and 3 have been canceled.

Claim 2 has been amended by incorporating the subject matter of claim 3.

Claim 4 has been rewritten in independent form.

Claims 5 and 6 have been amended to improve their form. No new matter has been added. Entry of the Amendment is respectfully submitted to be proper. Upon entry of the Amendment, claims 2 and 4-6 will be all the claims pending in the application.

**I. Claim Objections**

The Examiner has indicated that claims 3-6 will be objected to under 37 C.F.R. § 1.75 as being substantial duplicates of claim 2, if claim 2 is found allowable.

Applicants traverse in view of the following remarks.

Applicants respectfully submit that the compounds of currently presented claims 2 and 4-6 are directed to alpha and beta crystal forms of 1-(2-methoxyethyl)-2-methyl-4,9-dioxo-3-(pyrazin-2-ylmethyl)-4,9-dihydro-1H-naphtho[2,3-d]imidazol-3-ium bromide, respectively. The compounds are structurally different and recite PXD values which distinguish the compounds.

Therefore, the claims as amended are not duplicate claims. Withdrawal of the rejection is respectfully requested.

**II. Rejection Under 35 U.S.C. § 102(b)**

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by WO 2001/60803 ("Matsuhisa").

Applicants traverse and request reconsideration and withdrawal of the rejection in view of the amendments to the claims and in view of the following remarks.

Claim 1 has been canceled. The rejection of claim 1 is therefore moot.

Anticipation requires that a description of each element and limitation recited in a claim be disclosed in a single prior art reference. Claim 2 has been amended to incorporate the subject matter of claim 3, namely, the powder X-ray diffraction peak values of the crystal compound. At least for the reason that claim 3 is not rejected over Matsuhisa, the amendment to claim 2 renders the rejection moot. Furthermore, claim 2 does not read on compound 75 of Matsuhisa because Matsuhisa does not describe X-ray diffraction patterns as recited in claim 2. Also, Matsuhisa does not describe, teach or suggest X-ray crystallography. Thus, the present crystalline compound defined and characterized as having specific peaks of  $2\theta$  (°) = 8.5, 14.8, 19.7, 25.7 and 30.2 by powder X-ray diffraction does not read on the amorphous compound in Matsuhisa. Withdrawal of the rejection is respectfully requested.

### **III. Double Patenting Rejection**

Claims 1-6 are rejected on the ground of non-statutory obviousness-type double patenting as assertedly being unpatentable over claims 1-6 of U.S. Patent No. 6,734,203 ("the '203 Patent").

Applicants traverse and request reconsideration and withdrawal of the rejection in view of the amendments to the claims and in view of the following remarks.

Claims 1 and 3 have been canceled. Therefore, the rejection of claims 1 and 3 are therefore moot.

With respect to claims 2 and 4-6, Applicants respectfully submit that claims 2 and 4 have been amended to recite powder X-ray diffraction peak values of their respective alpha and beta forms. Matsuhisa does not render the present claims obvious because Matsuhisa does not describe, teach or suggest X-ray diffraction patterns or even X-ray crystallography of the compounds. Thus, the present crystalline compounds defined and characterized as having specific peaks of  $2\theta$  (°) = 8.5, 14.8, 19.7, 25.7 and 30.2 by powder X-ray diffraction are patentable over the subject matter taught in Matsuhisa.

Furthermore, one skilled in the pertinent art would not have been motivated to prepare the specific crystalline form of 1-(2-methoxyethyl)-2-methyl-4,9-dioxo-3-(pyrazin-2-ylmethyl)-4,9-dihydro-1H-naphtho[2,3-d]imidazol-3-ium bromide with the expectation of obtaining a pharmaceutically useful benefit, such as, the remarkable stability achieved during preservation and the unexpectedly superior properties achieved by crystalline forms. As shown in Test Example 2 in the present specification, the specific crystal of the present application did not

show degradation during its preservation. Additionally, the purity of the alpha and beta crystalline forms was retained.

Thus, there was no observation of an increase of impurity in which the imidazolium ring opened. On the contrary, an increase of impurity was observed with respect to Example 154, the chloride amorphous solid that is disclosed in the '203 patent.

#### IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

**65565**

CUSTOMER NUMBER

Sunhee Lee  
Registration No. 53,892

Date: July 14, 2008